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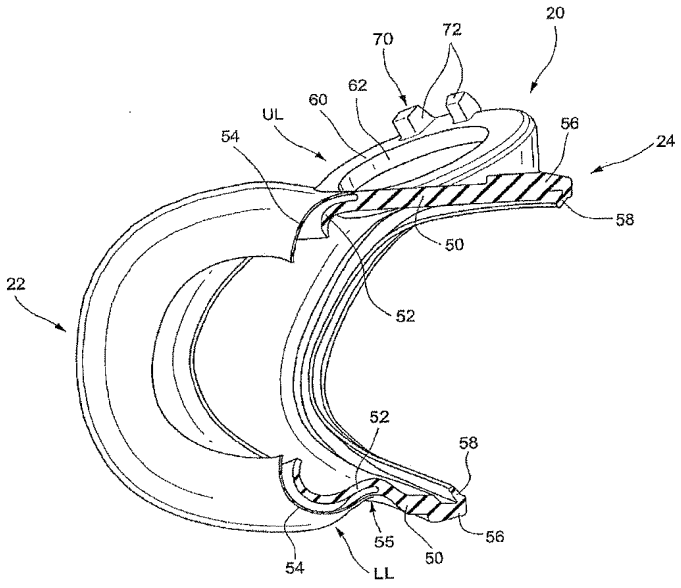

(57) Abstract: A mouth cushion (20) for a mask system includes a side wall (50), an undercushion (52) extending away from the side wall (50), and a membrane (54) provided to substantially surround the undercushion (52) and adapted to form a continuous seal around an exterior of a patient's mouth in use. The side wall (50) includes spaced-apart prong support structures (60) that provide annular recesses (62) adapted to support respective nasal prongs (30). Each prong support structure (60) includes an alignment indicator (70) to aid correct assembly of the respective nasal prong (30).

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CUSHION FOR MASK SYSTEM

CROSS-REFERENCE TO APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/848,360, filed October 2, 2006, which is incorporated herein by reference in its entirety.

[0002] Also, PCT Application No. PCT/AU2006/000770, filed June 6, 2006, and U.S. Application No. 11/447,295, filed June 6, 2006, are each incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0003] The present invention relates to a cushion for a mask system used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NIPPV).

BACKGROUND OF THE INVENTION

[0004] Mask systems form an interface between a patient and apparatus providing a supply of pressurized air or breathing gas and are hence sometimes referred to as patient interfaces. In this specification, the words mask system and patient interface may be used interchangeably. Mask systems in the field of the invention differ from mask systems used in other applications such as aviation and safety in particular because of their emphasis on comfort. This high level of comfort is desired because patients must sleep wearing the masks for hours, possibly each night for the rest of their lives. Mask systems typically, although not always, comprise (i) a rigid or semi-rigid portion often referred to as a shell or frame, (ii) a soft, patient contacting portion often referred to as a cushion, and (iii) some form of headgear to hold the frame and cushion in position. Mask systems often include a mechanism for connecting an air delivery conduit. The air delivery conduit is usually connected to a blower or flow generator.

[0005] A range of patient interfaces are known including nasal masks, nose & mouth masks, full face masks and nasal prongs, pillows, nozzles & cannulae. Masks typically cover more of the face than nasal prongs, pillows, nozzles and cannulae. In this specification, all will be collectively referred to as patient interfaces or mask systems. Nasal prongs, nasal pillows, nozzles and cannulae all will be collectively referred to as nasal prongs.

[0006] An inherent characteristic of *nasal* masks is that they do not seal the mouth region. A number of patients thus find that during sleep when muscles relax, mouth leak may occur. Alternatively, some patients are naturally mouth breathers and thus find a nasal mask type patient interface ineffective. Mouth leak is undesirable as, among other difficulties, it may result in noise, increased treatment pressure to compensate for the leak or an increased load on the nasal passages and potentially nasal obstruction or a runny nose. Full face masks or nose & mouth masks address this issue by sealing around both the nose and the mouth.

[0007] Leak is a problem common to all designs of patient interface. Since nasal bridge anthropometry varies greatly between patients, the soft patient contacting portion or cushion must adapt to the shapes of individual patients. Typically, this is not achieved for the entire range of patients and some form of leak occurs. The problem is heightened during sleep when the jaw moves and the head position changes. This action can often serve to dislodge the mask and cause leak. Since leak can be noisy and results in less-effective treatment, users often compensate by tightening the headgear more than is desired. This is detrimental for patient comfort and can cause skin breakdown or irritation.

[0008] A further problem encountered by patients who are using full face, nasal or nose and mouth masks is that the portion of the patient interface that seals around the nasal bridge prevents the patient from wearing spectacles. Additionally, it may give the sensation of being closed in, leading to a feeling of claustrophobia, particularly when combined with a mouth-sealing portion. A further disadvantage is that any leaks that may occur can affect the sensitive area surrounding the eyes.

[0009] Thus, there is a need for an improved mask system that does not suffer from the above-mentioned drawbacks.

SUMMARY OF THE INVENTION

[0010] One aspect of the present invention relates to a mouth cushion for a mask system. The mouth cushion includes a side wall, an undercushion extending away from the side wall, and a membrane provided to substantially surround the undercushion and adapted to form a continuous seal around an exterior of a patient's mouth in use. The side wall includes spaced-apart prong support structures that provide annular recesses adapted to support respective nasal prongs. Each prong support structure includes an alignment indicator to aid correct assembly of the respective nasal prong.

[0011] Another aspect of the present invention relates to a mouth cushion for a mask system. The mouth cushion includes a side wall, an undercushion extending away from the side wall, and a membrane provided to substantially surround the undercushion and adapted to form a continuous seal around an exterior of a patient's mouth in use. The side wall includes spaced-apart prong support structures that provide annular recesses adapted to support respective nasal prongs. Each prong support structure may includes an alignment indicator to aid correct assembly of the respective nasal prong. At least a portion of the undercushion includes a question-mark or sickle-shape configuration when in cross-section.

[0012] Another aspect of the present invention relates to a mask system for use between a patient and a device to deliver a breathable gas to the patient. The mask system includes a frame including a channel and a cushion provided to the frame. The cushion includes an end portion that is inserted and retained within the channel. The frame includes a recess that communicates with the channel and a hole that connects the recess to a frame exterior. The hole and recess provide an exit route for air contained within the channel.

[0013] Another aspect of the present invention relates to a nasal prong arrangement for a mask system. The nasal prong arrangement includes a pair of nasal prongs structured to sealingly communicate with nasal passages of the patient's nose in use. Each of the nasal prongs is adapted to be assembled to a support structure. Each of the nasal prongs includes at least one marking and/or tab that is adapted to aid alignment of each nasal prong with the support structure.

[0014] Another aspect of the present invention relates to a method for assembling a nasal prong to a cushion. The method includes assembling the nasal prong to a support structure provided to the cushion, and aligning a marking and/or tab provided to the nasal prong with an alignment indicator provided to the support structure.

[0015] Another aspect of the present invention relates to a mouth cushion for a mask system. The mouth cushion includes a side wall, an undercushion extending away from the side wall, and a membrane provided to substantially surround the undercushion and adapted to form a continuous seal around an exterior of a patient's mouth in use. The side wall includes spaced-apart prong support structures that provide annular recesses adapted to support respective nasal prongs. At least a portion of the undercushion includes structure to encourage bending in use.

[0016] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0018] Figs. 1-1 to 1-3 illustrate various views of a sealing assembly for a mask system including a cushion according to an embodiment of the present invention;

[0019] Figs. 2-1 to 2-7 illustrate various views of the cushion of the sealing assembly shown in Figs. 1-1 to 1-3 according to an embodiment of the present invention;

[0020] Figs. 3-1 to 3-2 illustrate various views of a frame of the sealing assembly shown in Figs. 1-1 to 1-3;

[0021] Figs. 4-1 to 4-3 illustrate various views of a cushion according to another embodiment of the present invention;

[0022] Figs. 5-1 to 5-4 illustrate various views of assembling a cushion to a frame according to an embodiment of the present invention;

[0023] Figs. 6-1 to 6-3 illustrate various views of a sealing assembly for a mask system including a cushion according to another embodiment of the present invention;

[0024] Fig. 7-1 is a perspective view of a paired prong arrangement according to an embodiment of the present invention;

[0025] Fig. 7-2 is a top view of a mask system illustrating the paired prong arrangement shown in Fig. 7-1 assembled to a cushion according to an embodiment of the present invention;

[0026] Fig. 8-1 is a cross-sectional view of a cushion according to another embodiment of the present invention;

[0027] Fig. 9-1 is a cross-sectional view of a cushion according to another embodiment of the present invention;

[0028] Fig. 9-2 is a schematic view of a cushion illustrating cross-sectional configuration around its circumference according to an embodiment of the present invention; and

[0029] Fig. 9-3 is a schematic view of a cushion illustrating cross-sectional configuration around its circumference according to another embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0030] Each illustrated embodiment includes features that may be used with the embodiments and/or components described in PCT Application No. PCT/AU2006/000770, filed June 6, 2006, and U.S. Application No. 11/447,295, filed June 6, 2006, as would be apparent to those of ordinary skill in the art. PCT Application No. PCT/AU2006/000770 and U.S. Application No. 11/447,295 are each incorporated herein by reference in its entirety.

[0031] The following illustrates several alternative embodiments of the present invention, which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, each single feature or combination of features in any of the embodiments may constitute an additional embodiment.

1. Sealing Assembly

[0032] Figs. 1-1 to 1-3 illustrate a sealing assembly 10 for a mask system that includes a cushion 20 according to an embodiment of the present invention. The sealing assembly 10 is structured to provide an effective seal with both the patient's mouth and the patient's nasal passages in use. The sealing assembly 10 is adapted to be coupled to an elbow assembly, e.g., swivel elbow, that delivers breathable gas to the patient, and a headgear assembly that maintains the sealing assembly 10 in a desired position on the patient's face.

[0033] The sealing assembly 10 includes a mouth cushion 20 structured to sealingly engage around an exterior of a patient's mouth in use and a pair of nasal prongs 30 structured to sealingly communicate with the nasal passages of the patient's nose in use. The cushion 20 is structured to be removably and replaceably attached to a substantially rigid frame 40 (see Figs. 3-1 and 3-2).

[0034] Further details and embodiments of this type of mask system including further details and embodiments of nasal prongs and frames are disclosed in the above noted PCT Application No. PCT/AU2006/000770 and U.S. Application No. 11/447,295.

1.1 First Embodiment of Mouth Cushion

[0035] Figs. 2-1 to 2-7 illustrate the mouth cushion 20 of the sealing assembly according to an embodiment of the present invention. As illustrated, the mouth cushion 20 includes a face-contacting portion 22 and a non-face-contacting portion 24.

[0036] As best shown in Figs. 2-6 and 2-7, the face-contacting portion 22 of the cushion 20 includes a side wall 50, an undercushion 52 extending away from the side wall 50, and a membrane 54 provided to substantially surround the undercushion 52 and provide a sealing structure for the face-contacting portion 22. The inner edge of the membrane 54 defines an aperture 57 that receives the patient's mouth (see Figs. 2-1 and 2-3).

[0037] The non-face-contacting portion 24 is structured to be removably and replaceably attached to the frame 40. As best shown in Figs. 3-1 and 3-2, the frame

40 includes a main body 44 having a side frame portion 46 on each lateral side thereof. The main body 44 includes an aperture 45 and a flanged collar member 47 adapted to engage an elbow. Also, each side frame portion 46 includes headgear attachment points, e.g., upper and lower anchors 48, 49, for attaching a headgear assembly. Such a frame arrangement is disclosed in the above noted PCT Application No. PCT/AU2006/000770 and U.S. Application No. 11/447,295.

[0038] In the illustrated embodiment, the non-face-contacting portion 24 includes an arrow-head type design having a tapered end portion 56 with a sealing lip 58 (see Figs. 2-6 and 2-7). The tapered end portion 56 is adapted to be easily inserted and retained within a channel provided on the frame 40 in manner as described below.

1.1.1 Alignment Indicators

[0039] The side wall 50 of the cushion 20 includes spaced-apart prong support structures 60 that provide annular recesses 62 adapted to support respective prongs 30. As illustrated, the prong support structures 60 provide an angled pedestal that project the prongs 30 at the correct angle to the patient's nares (e.g., see Figs. 1-1 to 1-2).

[0040] Moreover, each prong support structure 60 includes an alignment indicator 70 to aid correct assembly of the respective prong 30. Specifically, each alignment indicator 70 includes spaced-apart tabs or protrusions 72. The spaced-apart tabs 72 protrude from a top wall of the prong support structure 60 adjacent the recess 62. Also, the alignment indicator 70 is provided to a side of the prong support structure 60 that is easy visible, e.g., oriented along the side of the cushion 20.

[0041] In use, the alignment indicators 70 provide a visual and tactile feedback system to aid assembly of the prongs 30 to the mouth cushion 20. This arrangement may be particularly helpful since the prongs 30 may be molded straight, e.g., see Fig. 7-1, and then flexed on assembly to the mouth cushion 20.

[0042] In an alternative embodiment, each prong 30 may include a marking that is adapted to align with a respective alignment indicator 70. In a further alternative embodiment, each prong 30 may include a tab that is adapted to engage a respective alignment indicator 70 to aid correct assembly. In embodiments, each prong may include multiple markings and/or multiple tabs that allows one of multiple positions or angles of the prong to be selected for assembly.

[0043] For example, Fig. 7-1 illustrates a paired-prong arrangement including prongs 30 joined by a bridging or connecting strap 32. As illustrated, each prong 30 includes a tab 35 that extends radially outwardly from a base portion thereof. When the paired-prong arrangement is assembled to the cushion 20, as shown in Fig. 7-2, the tab 35 of each prong 30 engages a respective alignment indicator 70 to aid correct assembly, e.g., tab 35 extends between the spaced-apart tabs 72. It should be understood that such a tab arrangement may be provided to a single-prong arrangement that is molded and assembled individually to the cushion 20.

1.1.2 Cushion Profile

[0044] The profile of the cushion 20 is structured to provide a better seal and may include characteristics and/or features similar to the cushion profile disclosed in PCT/AU2006/000032, filed January 12, 2006, which is incorporated herein by reference in its entirety.

[0045] Fig. 2-6 illustrates a cross-section of the cushion 20 between the prong support structures 60. As illustrated, at the upper lip section UL of the cushion profile, the side wall 50, undercushion 52, and membrane 54 are all generally aligned in a relatively straight profile. However, at the lower lip section LL of the cushion profile, the lower portion of the undercushion 52 has a more arcuate, e.g., semi-circular, question-mark, sickle-shape, configuration that defines a space 55 below a lower portion of the undercushion 52 and adjacent the side wall 50. This arcuate configuration provides greater flexibility or range of movement to the undercushion 52 in use.

[0046] That is, the arcuate configuration provides a spring structure that encourages the cushion wall to resiliently bend rather than buckle. It should be appreciated that the cushion wall may have other suitable configurations to achieve this spring structure or flexibility, e.g., arcuate configuration, varying wall thickness, bellows arrangement, etc.

[0047] Moreover, this cushion profile provides a seal that accommodates a wide range of facial profiles, facilitates set-up and achievement of a seal, and accommodates movement of the patient's face during use.

[0048] The arcuate configuration is also provided at the sides of the cushion 20, i.e., in the cheek sections C, as shown in Fig. 2-7. In addition, the cushion 20 may be designed at an angle α steeper than the majority of facial profiles to provide an initial contact on the cheeks of the patient and thus ensure a strong seal at these points. In an embodiment, the angle α in Fig. 2-7 may be in the range of 30-50°, e.g., 40°.

[0049] Also, Figs. 2-4 and 2-5 illustrate the cushion 20 (in solid lines) with respect to a cushion (in dashed lines) disclosed in the above noted PCT Application No. PCT/AU2006/000770 and U.S. Application No. 11/447,295.

1.2 Second Embodiment of Mouth Cushion

[0050] Figs. 4-1 to 4-3 illustrate a cushion 220 according to another embodiment of the present invention. In this embodiment, no arcuate configuration is provided over a short distance at the upper lip and lower lip sections UL, LL of the cushion profile. The arcuate configuration is provided at the sides of the cushion 220, which then slowly blends to a flat configuration over a short distance at the top and bottom lip sections.

[0051] Specifically, as shown in Fig. 4-2, the side wall 250, undercushion 252, and membrane 254 at the upper lip and lower lip sections UL, LL are all generally aligned in a relatively straight profile. As shown in Fig. 4-3, the lower portion of the undercushion 252 at the cheek sections C has a more arcuate, e.g., semi-circular, question-mark, sickle-shape, configuration that provides greater flexibility to the undercushion 252 in use.

[0052] The combination of the arcuate configuration at the cheek sections C and a steeper cushion angle previously discussed provide an improved seal and fit of the cushion 220. The arcuate configuration at the cheek sections C of the cushion 220 are typically the first section of the cushion 220 to contact the patient's face and the arcuate configuration at the cheek sections C then deform as required to allow the cushion 220 to be fitted to the upper lip and lower lip sections UL, LL. The last points of contact are thus the more sensitive areas of the patient's face, i.e., the upper lip and lower lip sections UL, LL. The adjustability in the cheek regions C provided by the arcuate configuration allows the patient to finely adjust the cushion 220 to

comfortably fit and seal in these sensitive regions of the upper lip and lower lip sections UL, LL while still maintaining a cheek seal without excessive force.

1.3 Cushion Assembly to Frame

[0053] Figs. 5-1 to 5-4 illustrate assembly of a cushion to a frame according to an embodiment of the present invention. In the illustrated embodiment, the cushion is in the form of cushion 220 described above and indicated with similar reference numerals. The frame 240 is similar to frame 40 described above. In contrast, the frame 240 includes two ports 242, e.g., tubular spigots, located in recesses in the base of the frame 240. It should be appreciated that cushion 20 may be attached to frame 240 in a similar manner, and that cushions 20, 220 may be attached to frame 40 in a similar manner.

[0054] As illustrated, the tapered end portion 256 is adapted to be easily inserted and retained within a channel 280 provided on the frame 240. The sealing lip 258 provides a seal around the perimeter of the cushion 220 and also in conjunction with the bead 282 (see Fig. 5-4) around the frame channel 280 retains the cushion 220 onto the frame 240.

[0055] In addition, a recess 285 is provided to the frame 240 and communicates with the channel 280 that retains the cushion 220, as best shown in Fig. 5-4. The recess 285 forms a smaller channel around the bottom of the channel 280. Also, a hole 290 is provided below the ports 242 which connects the recess or channel 285 to the exterior of the frame 240 (see Figs. 5-1, 5-2, and 5-4). It should be appreciated that the hole 290 may be located at any position around the channel 280.

[0056] In manufacturing assembly, a vacuum is applied around the hole 290 which in turn creates a vacuum around the channel 285 drawing the cushion 220 into the fully seated position. The hole 290 and channel 285 also help standard assembly by allowing an exit route for the air contained within channel 280 and thus leading to less force required to assemble the cushion 220 to the frame 240. In this embodiment, the channel 285 has a tapered hole, e.g., exit diameter about 1.0 – 1.3 mm, e.g., 1.16 mm. In alternative embodiments, the hole diameter may vary and multiple holes and/or a deeper/varying section channel may be provided.

1.4 Third Embodiment of Mouth Cushion

[0057] Figs. 6-1 to 6-3 illustrate a cushion 320 according to another embodiment of the present invention. In this embodiment, each side of the cushion 330 includes a support strut or rib 325. As illustrated, the support strut 325 extends generally horizontally along an exterior surface of the respective side of the cushion 320. In use, the support strut 325 may modify the deflection characteristic of the cushion 320. It should be appreciated that the support strut 325 may have other suitable shapes, arrangements, and positioning along the cushion 320 to modify the deflection characteristic. In addition, one or more support struts may be provided to modify the deflection characteristic.

1.5 Alternative Embodiments of Mouth Cushion

[0058] Fig. 8-1 illustrates a cross-section of a mouth cushion 420 according to an alterative embodiment of the present invention. As illustrated, the cushion cross-section includes a side wall 450, undercushion 452, and membrane 454. The undercushion 452 has a more arcuate, e.g., semi-circular, question-mark, sickle-shape, configuration (e.g., in the lower lip section) that provides flexibility to the cushion 420 without extending the footprint of the cushion 420. That is, the cushion 420 may retain the same overall height.

[0059] Fig. 9-1 illustrates a cross-section of a mouth cushion 520 according to another alterative embodiment of the present invention. As illustrated, the cushion cross-section includes a side wall 550, undercushion 552, and membrane 554. The undercushion 552 has a more arcuate, e.g., semi-circular, question-mark, sickle-shape, configuration that provides flexibility to the cushion 520.

[0060] In an embodiment, the arcuate configuration, e.g., sickle-shaped cross-section, may be provided around a majority of the cushion circumference, as shown in a bold line in Fig. 9-2. Alternatively, the arcuate configuration, e.g., sickle-shaped cross-section, may be provided around the entirety of the cushion circumference, as shown in a bold line in Fig. 9-3. Depending on the radius of curvature of the arcuate shape, this arrangement may have a contact point on the patient's face outside of that which would be achieved with a cushion having a cross-section such as that shown in

Fig. 4-2 for example. This allows the frame to be smaller, thereby providing less weight and visually reducing the mask for the patient.

[0061] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike.

WHAT IS CLAIMED IS:

1. A mouth cushion for a mask system, the mouth cushion comprising:

a side wall;

an undercushion extending away from the side wall; and

a membrane provided to substantially surround the undercushion and adapted to form a continuous seal around an exterior of a patient's mouth in use,

wherein the side wall includes spaced-apart prong support structures that provide annular recesses adapted to support respective nasal prongs, and each prong support structure includes an alignment indicator to aid correct assembly of the respective nasal prong.

2. The mouth cushion according to claim 1, wherein the prong support structures provide an angled pedestal that project the nasal prongs at an angle to the patient's nares.

3. The mouth cushion according to any one of claims 1-2, wherein each alignment indicator includes spaced-apart tabs or protrusions.

4. The mouth cushion according to claim 3, wherein the tabs or protrusions protrude from a top wall of the prong support structure adjacent the recess.

5. The mouth cushion according to any one of claims 1-4, wherein at least a portion of the undercushion includes a question-mark or sickle-shape configuration.

6. The mouth cushion according to claim 5, wherein the undercushion includes a question-mark or sickle-shape configuration in a lower lip section.

7. The mouth cushion according to any one of claims 5-6, wherein the undercushion includes a question-mark or sickle-shape configuration in cheek sections.

8. The mouth cushion according to any one of claims 1-7, wherein the membrane in each cheek section defines an angle with respect to a longitudinal axis of about 30-50°.

9. The mouth cushion according to claim 8, wherein the membrane in each cheek section defines an angle with respect to a longitudinal axis of about 40°.

10. The mouth cushion according to any one of claims 1-9, further comprising a support strut or rib along opposing side walls thereof.

11. A mouth cushion for a mask system, the mouth cushion comprising:

a side wall;

an undercushion extending away from the side wall; and

a membrane provided to substantially surround the undercushion and adapted to form a continuous seal around an exterior of a patient's mouth in use,

wherein the side wall includes spaced-apart prong support structures that provide annular recesses adapted to support respective nasal prongs, and

at least a portion of the undercushion includes a question-mark or sickle-shape configuration when in cross-section.

12. The mouth cushion according to claim 11, wherein the undercushion includes a question-mark or sickle-shape configuration in a lower lip section.

13. The mouth cushion according to any one of claims 11-12, wherein the undercushion includes a question-mark or sickle-shape configuration in cheek sections.

14. The mouth cushion according to any one of claims 11-13, wherein the membrane in each cheek section defines an angle with respect to a longitudinal axis of about 30-50°.

15. The mouth cushion according to claim 14, wherein the membrane in each cheek section defines an angle with respect to a longitudinal axis of about 40°.

16. A mask system for use between a patient and a device to deliver a breathable gas to the patient, the mask system comprising:

a frame;

a mouth cushion according to any one of claims 1-15 provided to the frame; and

a pair of nasal prongs provided to respective prong support structures of the mouth cushion.

17. The mask system according to claim 16, wherein each prong includes a tab that engages a respective alignment indicator provided to the mouth cushion.

18. The mask system according to any one of claims 16-17, wherein the mouth cushion includes a tapered end portion with a sealing lip, the tapered end portion adapted to be inserted and retained within a channel provided to the frame.

19. The mask system according to claim 18, wherein the sealing lip provides a seal around the perimeter of the cushion.

20. The mask system according to any one of claims 18-19, wherein the frame includes a recess that communicates with the channel and a hole that connects the recess to a frame exterior.

21. The mask system according to claim 20, wherein the hole and recess provide an exit route for air contained within the channel.

22. The mask system according to any one of claims 20-21, wherein the recess is tapered.

23. A mask system for use between a patient and a device to deliver a breathable gas to the patient, the mask system comprising:

a frame including a channel; and

a cushion provided to the frame, the cushion including an end portion that is inserted and retained within the channel,

wherein the frame includes a recess that communicates with the channel and a hole that connects the recess to a frame exterior, the hole and recess providing an exit route for air contained within the channel.

24. A nasal prong arrangement for a mask system, the nasal prong arrangement comprising:

a pair of nasal prongs structured to sealingly communicate with nasal passages of the patient's nose in use,

each of the nasal prongs adapted to be assembled to a support structure, and each of the nasal prongs including at least one marking and/or tab that is adapted to aid alignment of each nasal prong with the support structure.

25. A method for assembling a nasal prong to a cushion, the method comprising:

assembling the nasal prong to a support structure provided to the cushion; and

aligning a marking and/or tab provided to the nasal prong with an alignment indicator provided to the support structure.

26. A mouth cushion for a mask system, the mouth cushion comprising:

a side wall;

an undercushion extending away from the side wall; and

a membrane provided to substantially surround the undercushion and adapted to form a continuous seal around an exterior of a patient's mouth in use,

wherein the side wall includes spaced-apart prong support structures that provide annular recesses adapted to support respective nasal prongs, and

at least a portion of the undercushion includes structure to encourage bending in use.

27. A cushion for a respiratory mask used in treatment of sleep disordered breathing including a sidewall portion defining a spring structure arranged to progressively resiliently bend in use.

28. The cushion of claim 27 wherein the sidewall portion has a sickle shape.

29. The cushion of claim 27 wherein the sidewall portion is designed to progressively bend rather than buckle in use.

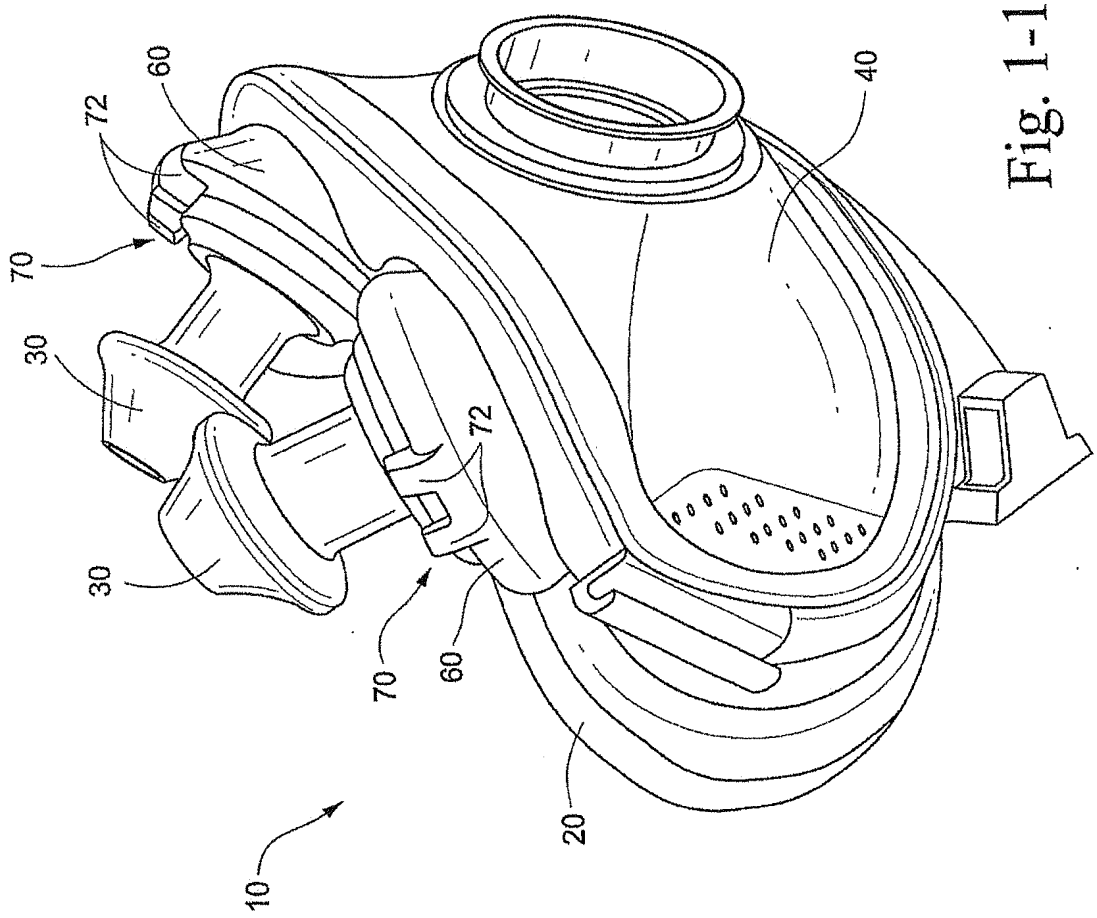


Fig. 1-1

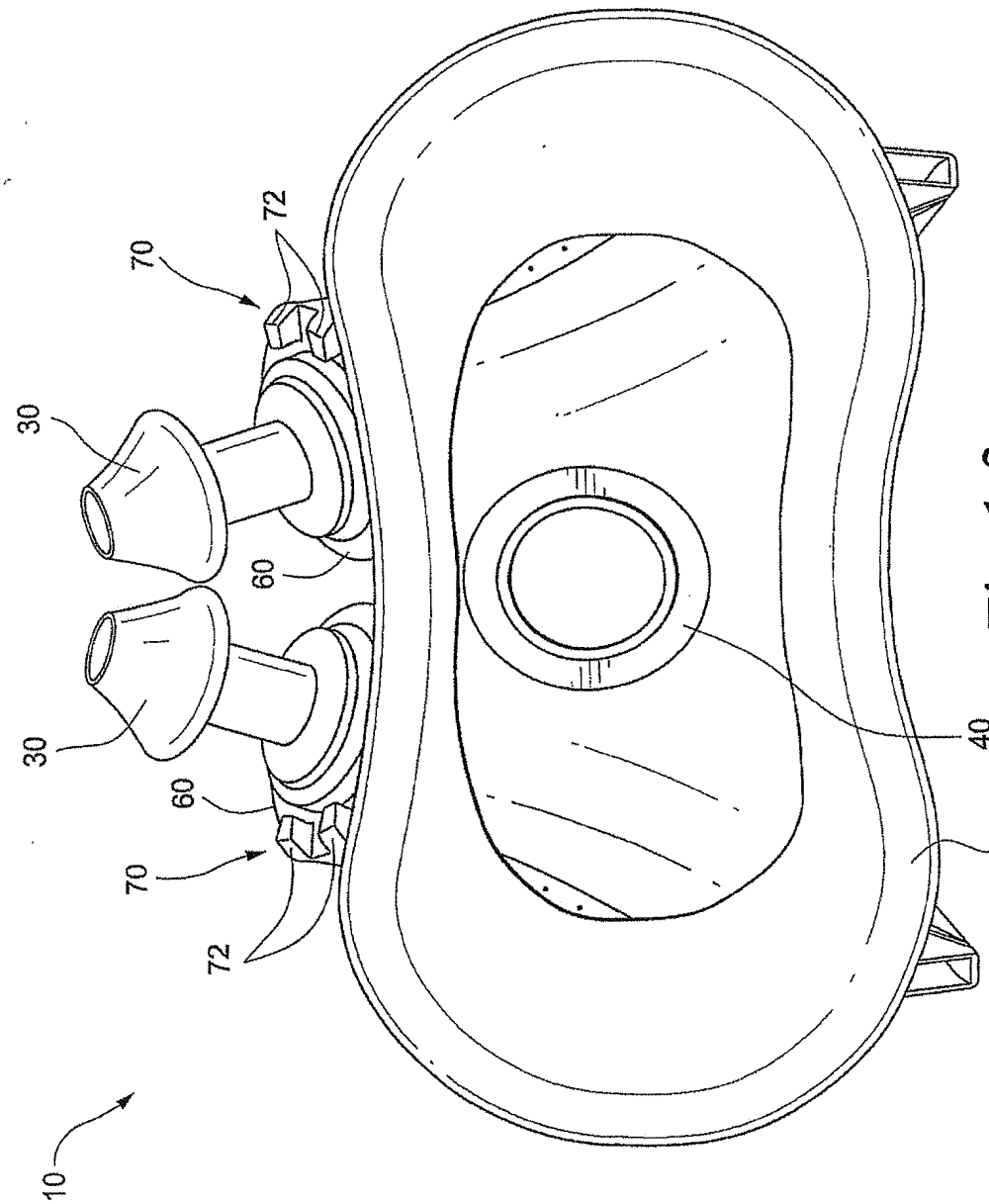


Fig. 1-2

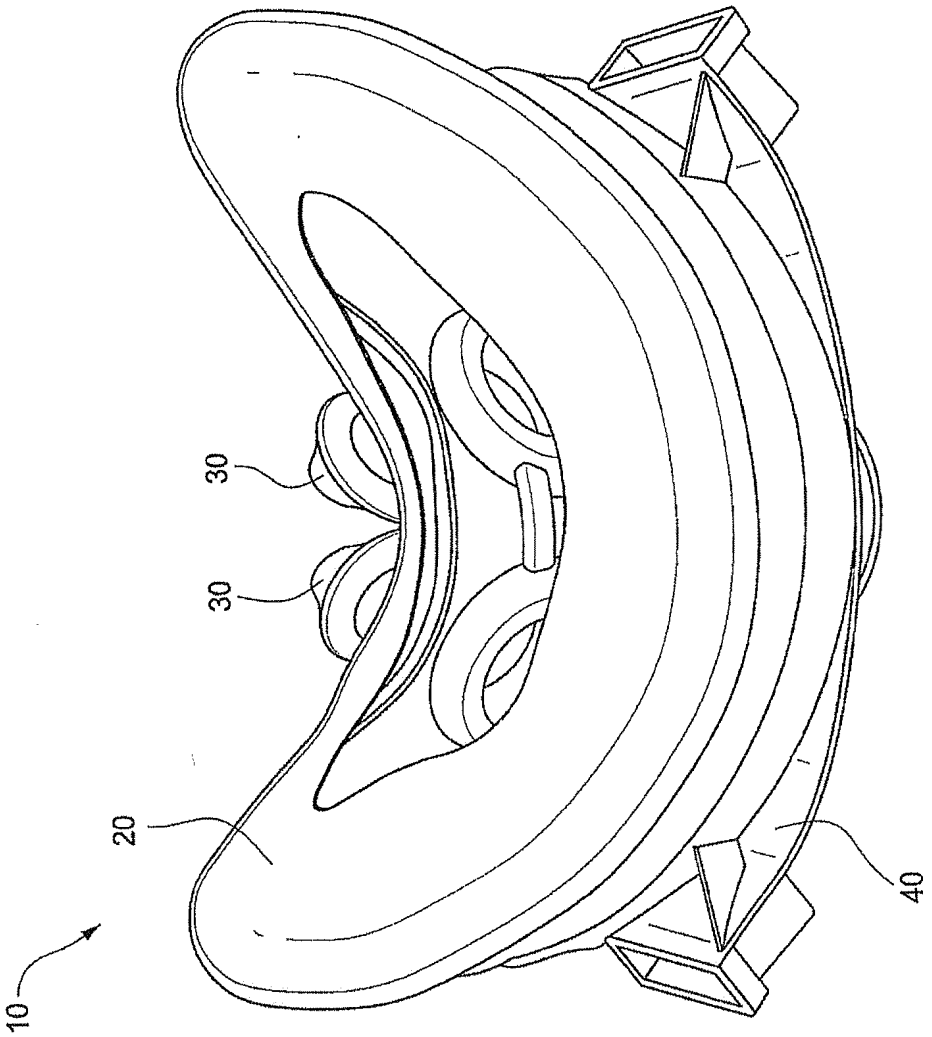


Fig. 1-3

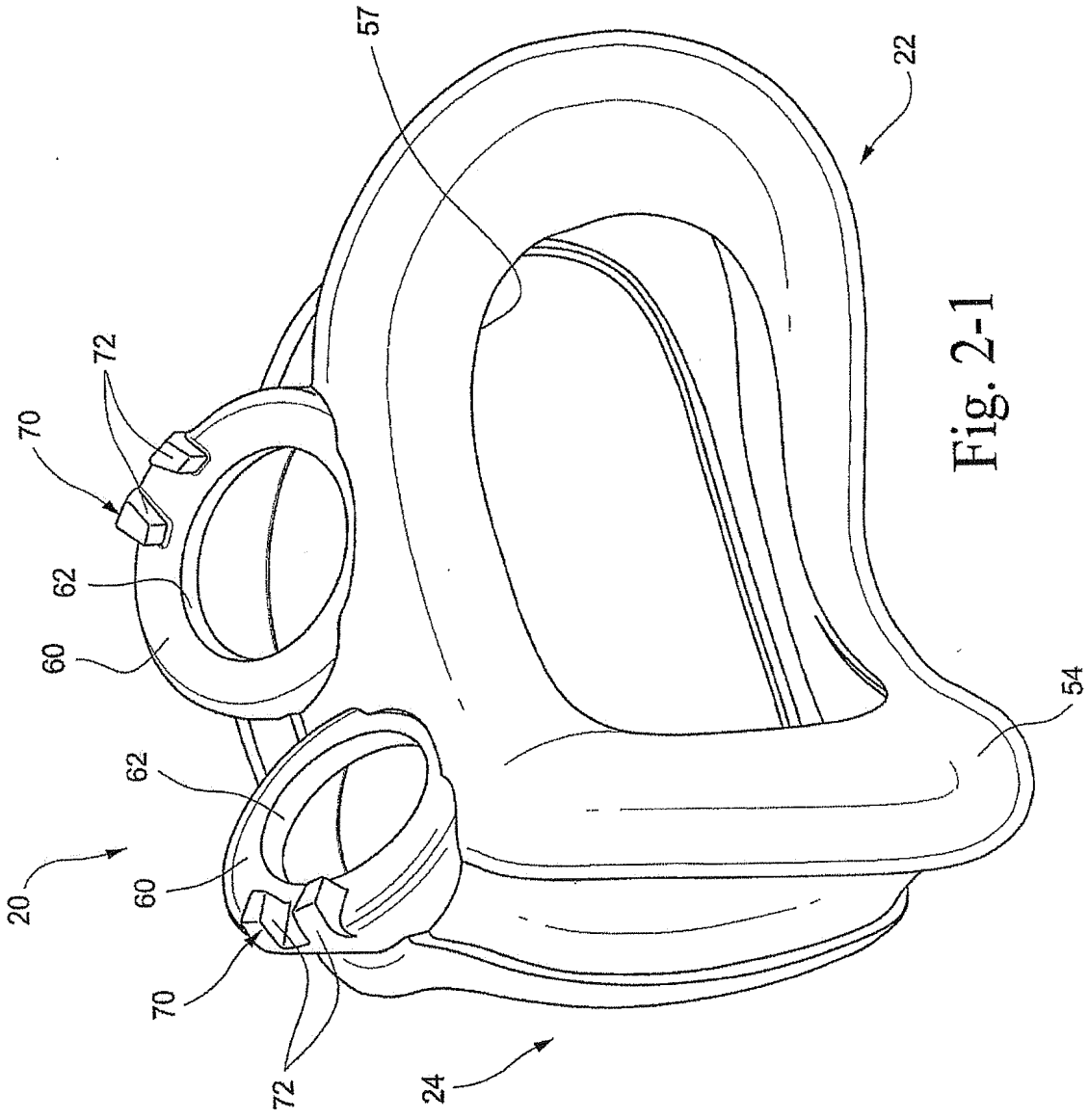


Fig. 2-1

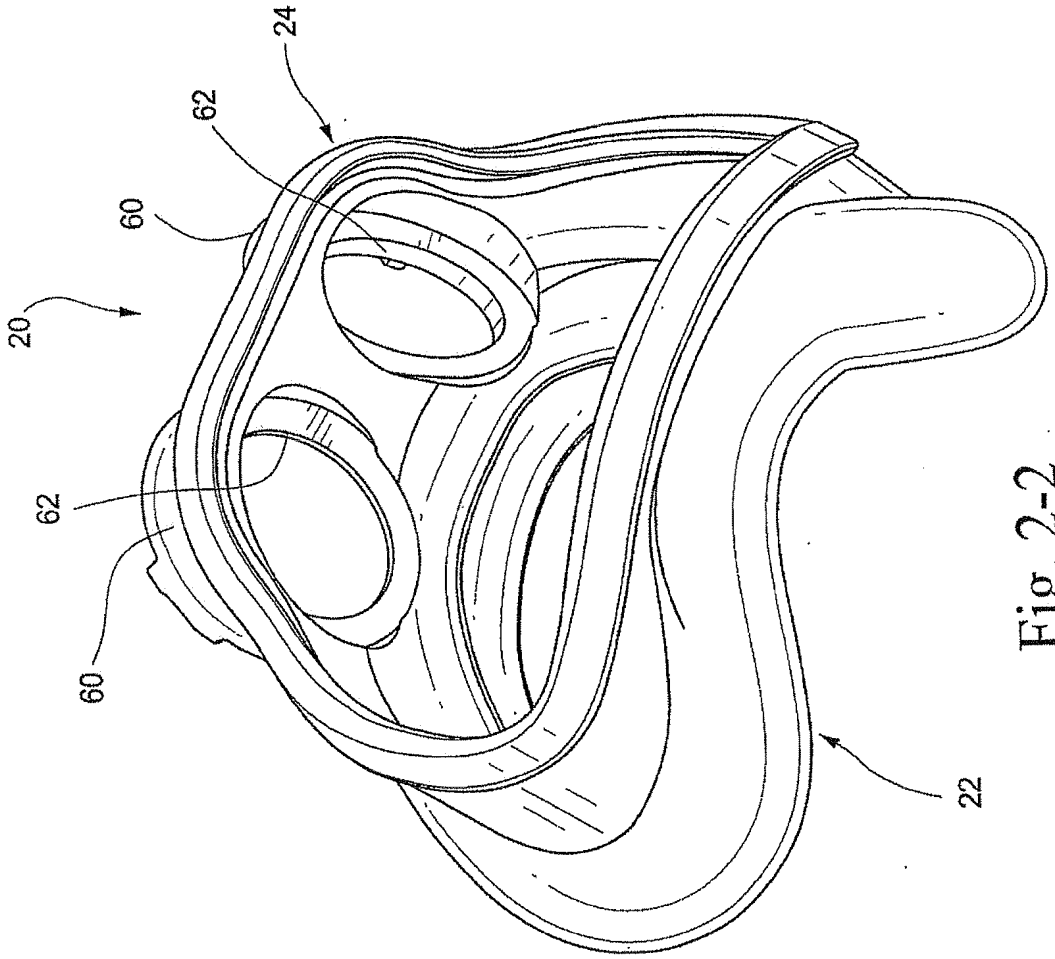


Fig. 2-2

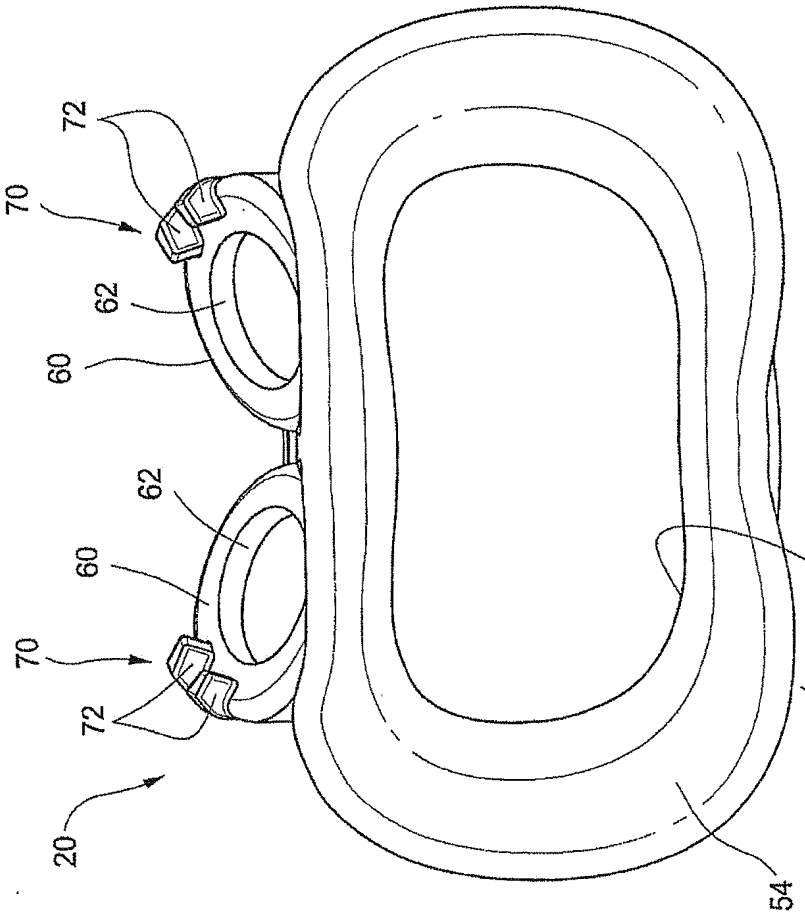


Fig. 2-3

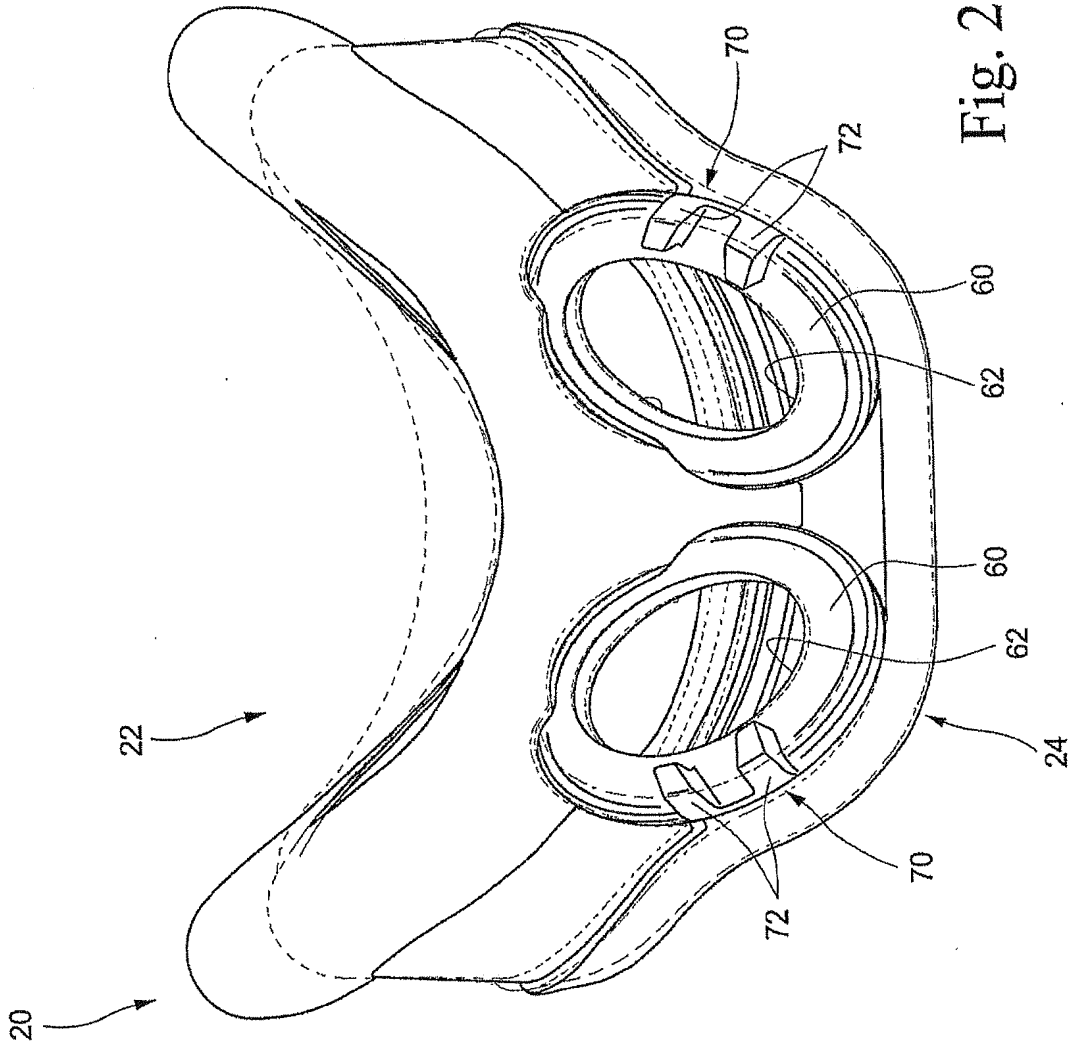


Fig. 2-4

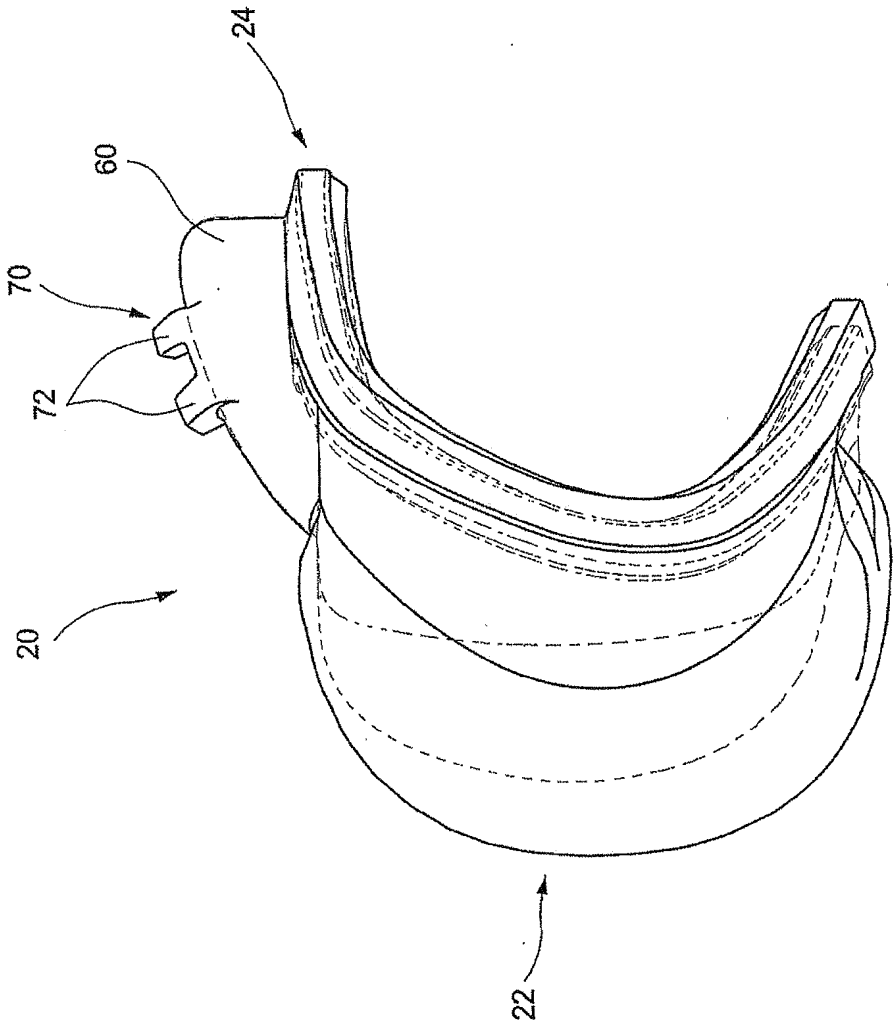


Fig. 2-5

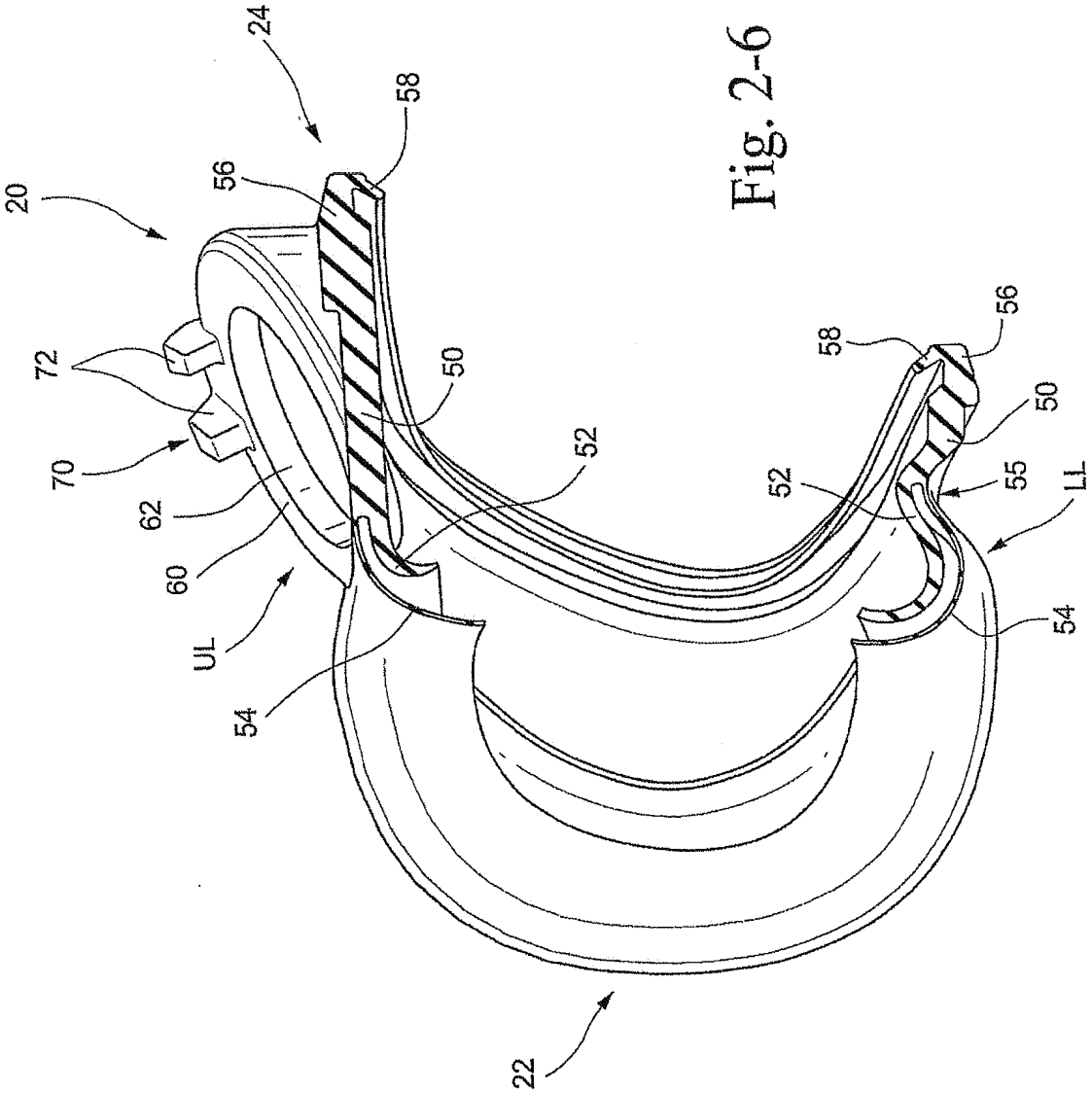


Fig. 2-6

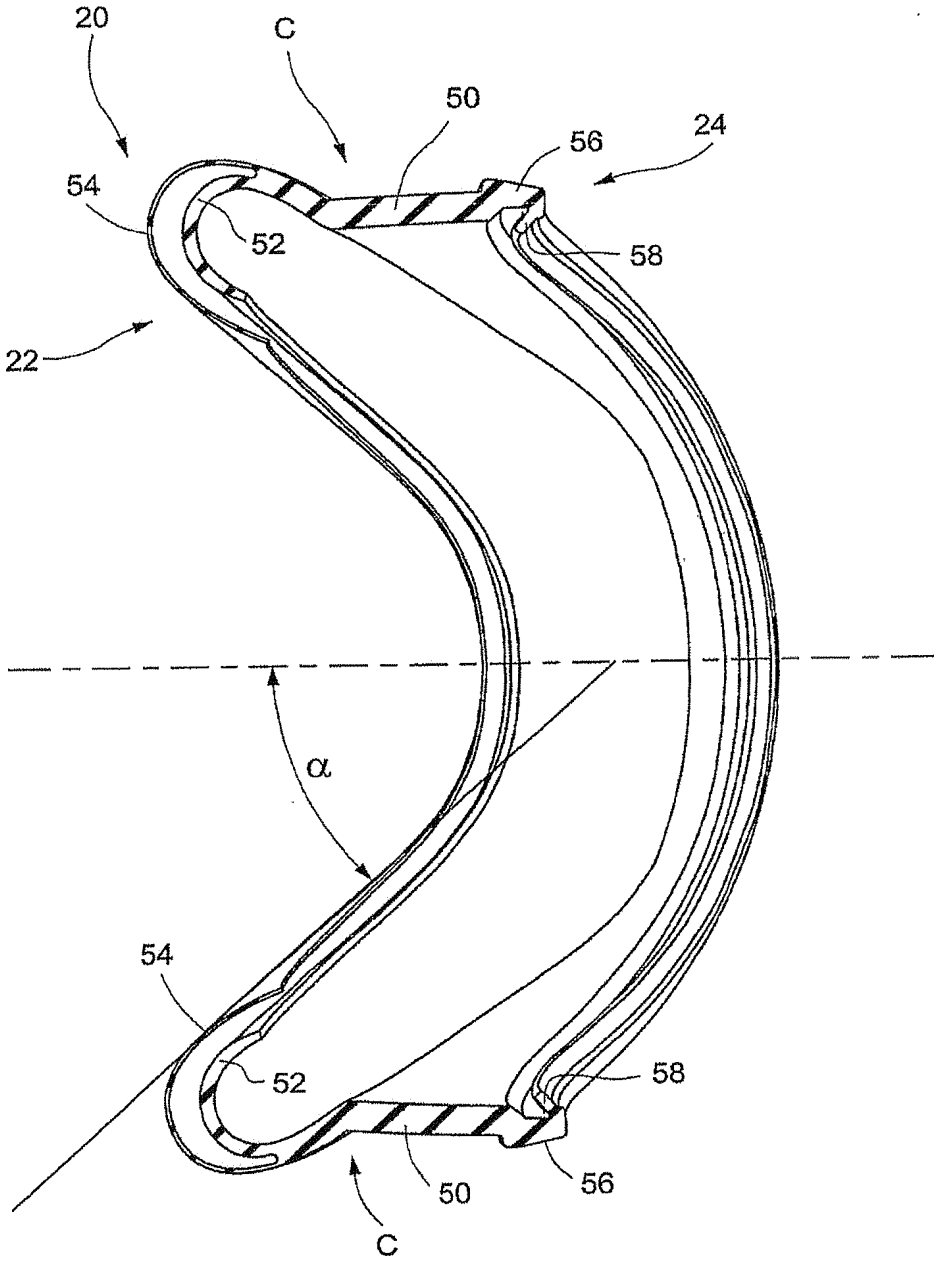


Fig. 2-7

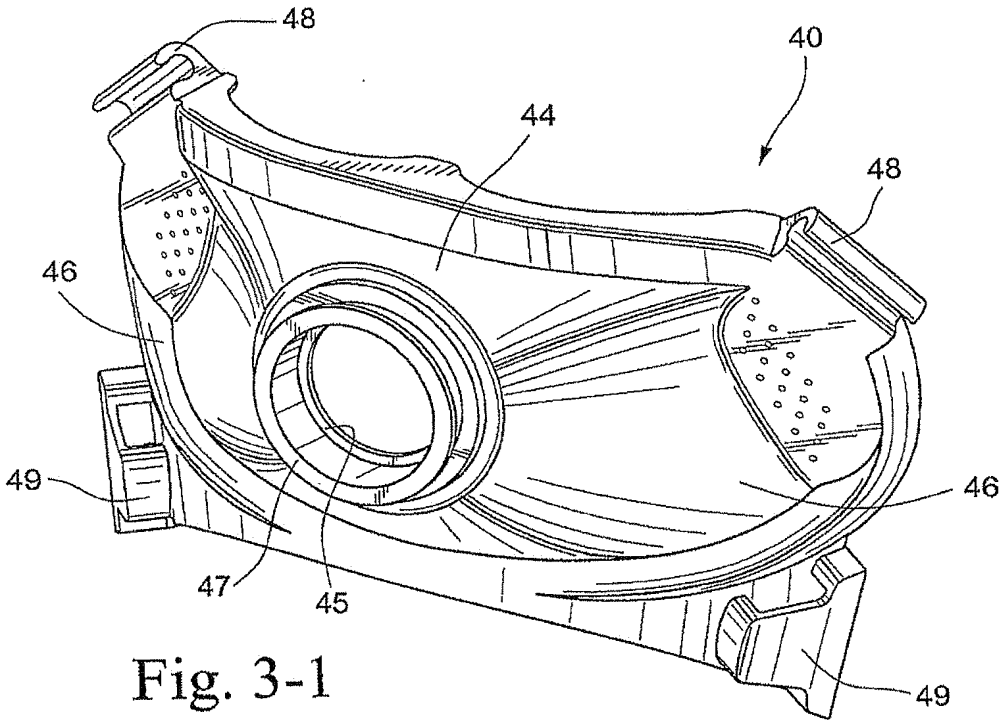


Fig. 3-1

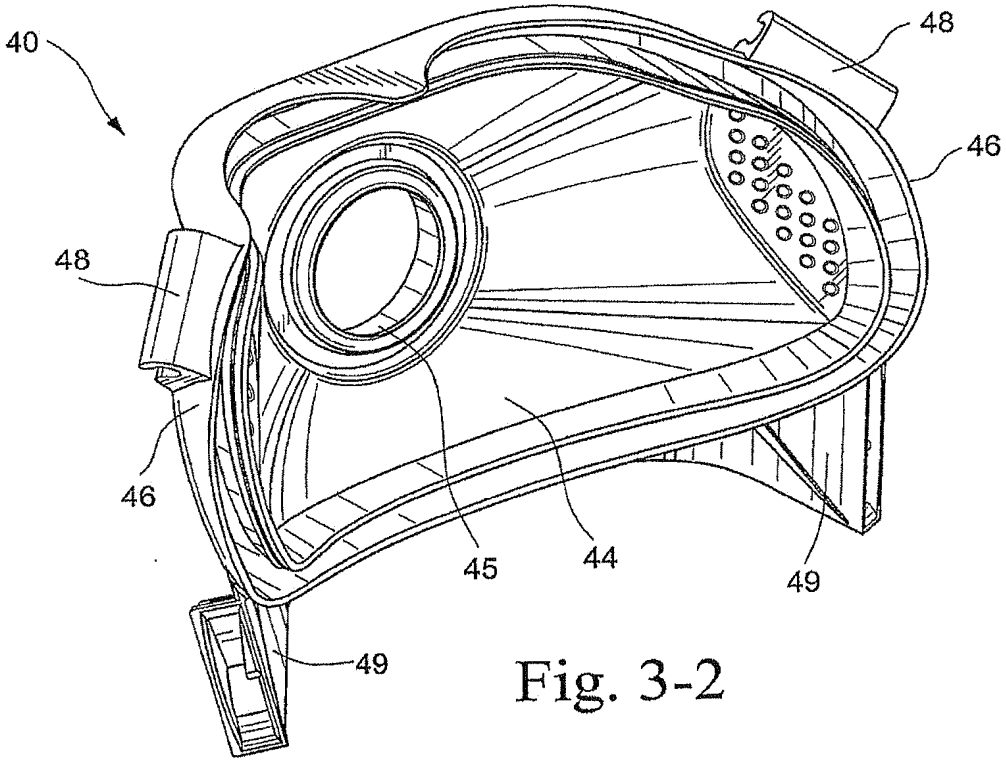


Fig. 3-2

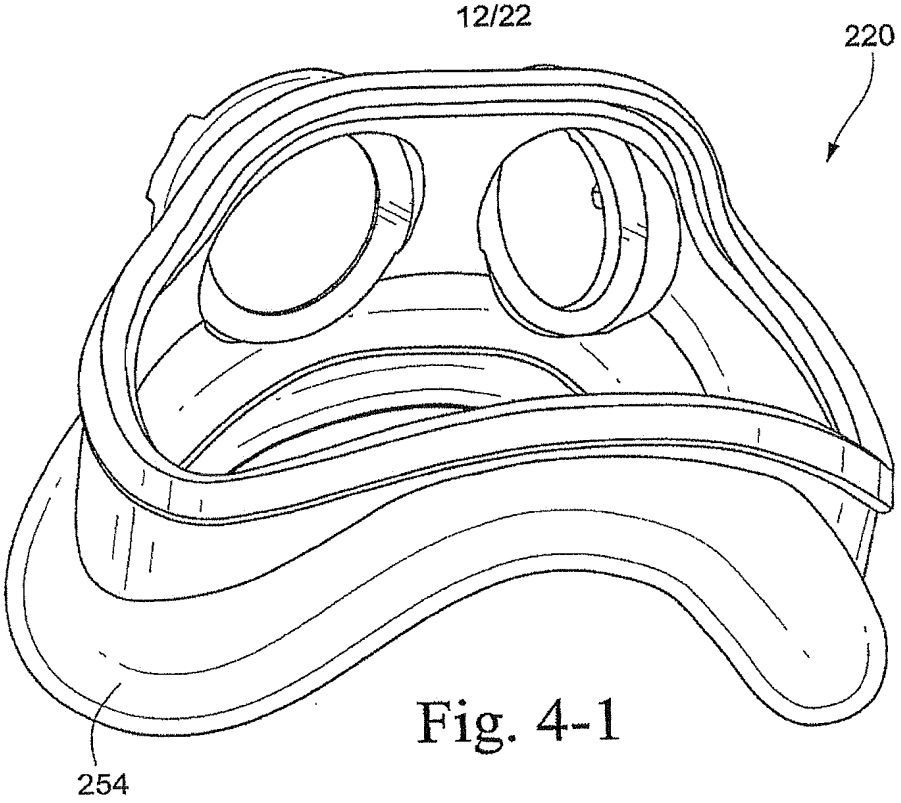


Fig. 4-1

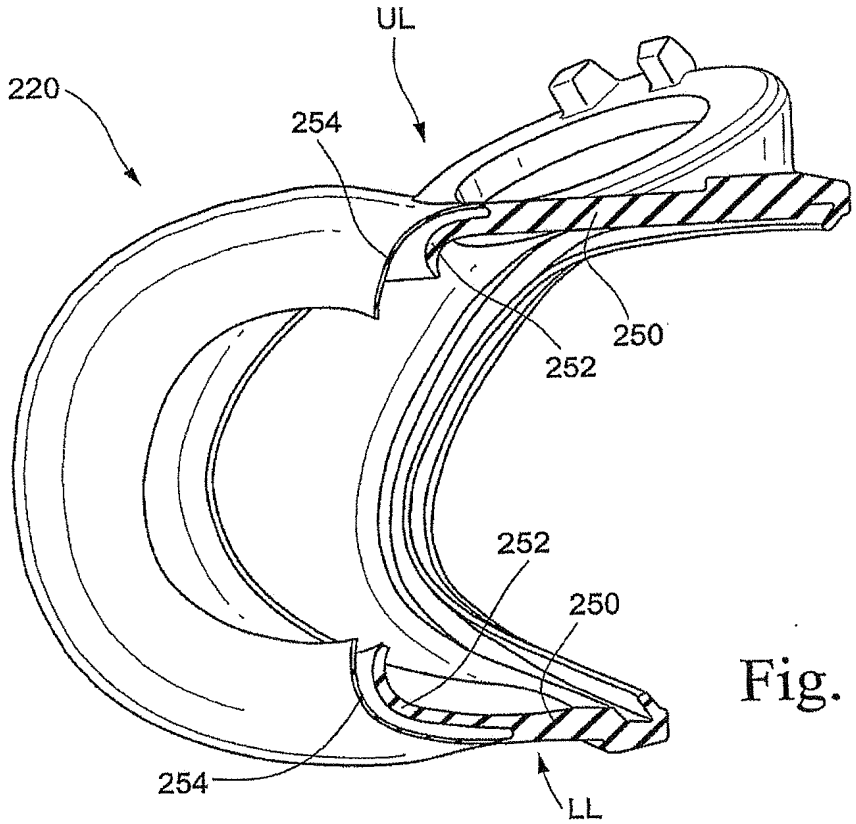


Fig. 4-2

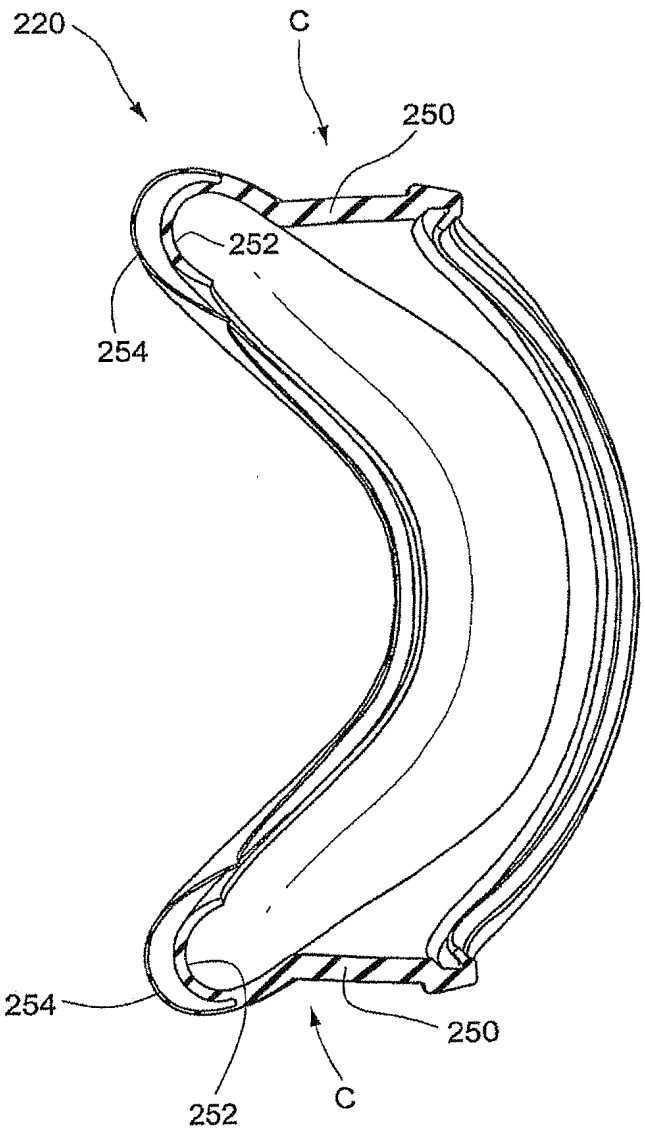


Fig. 4-3

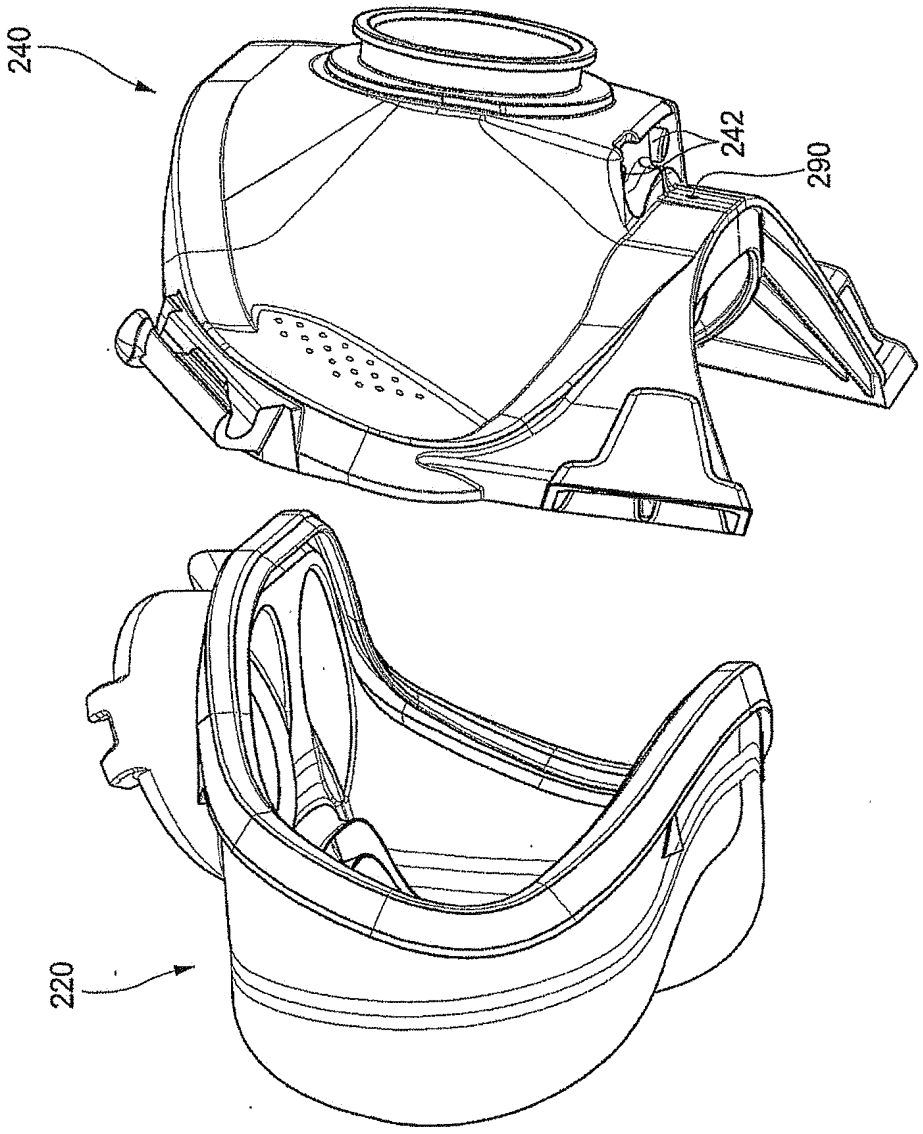


Fig. 5-1

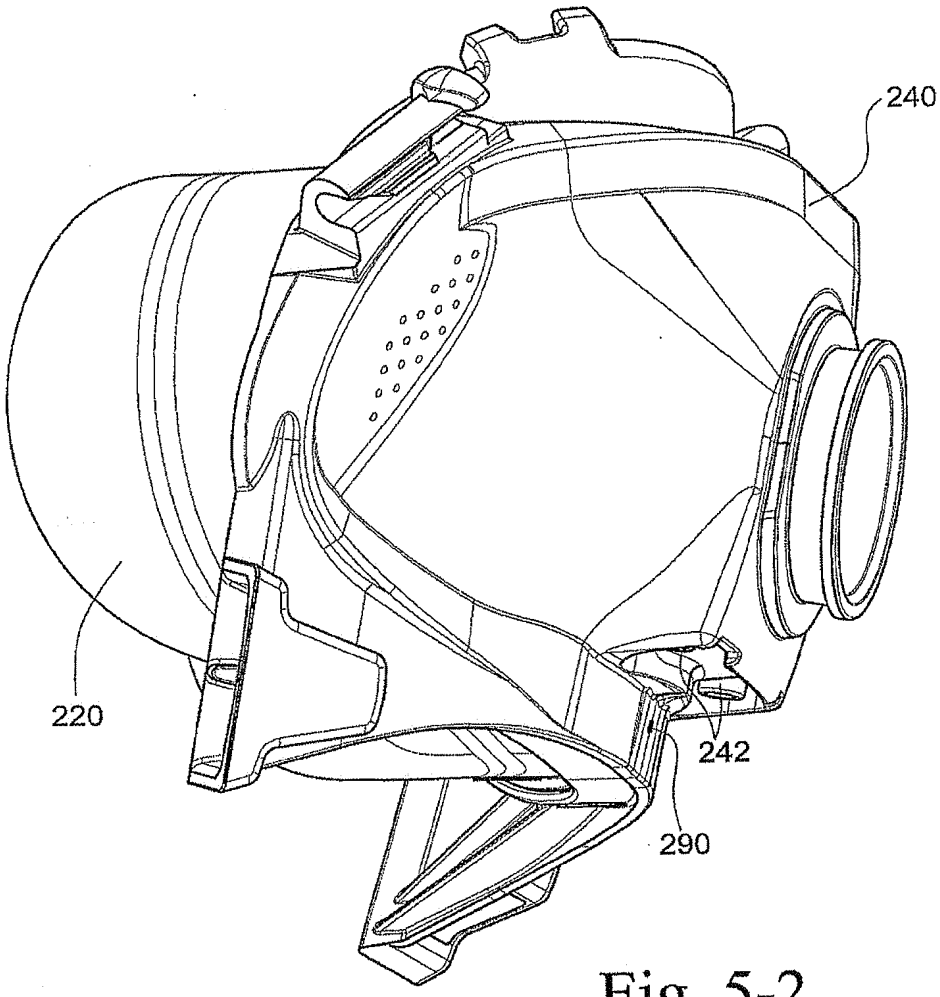
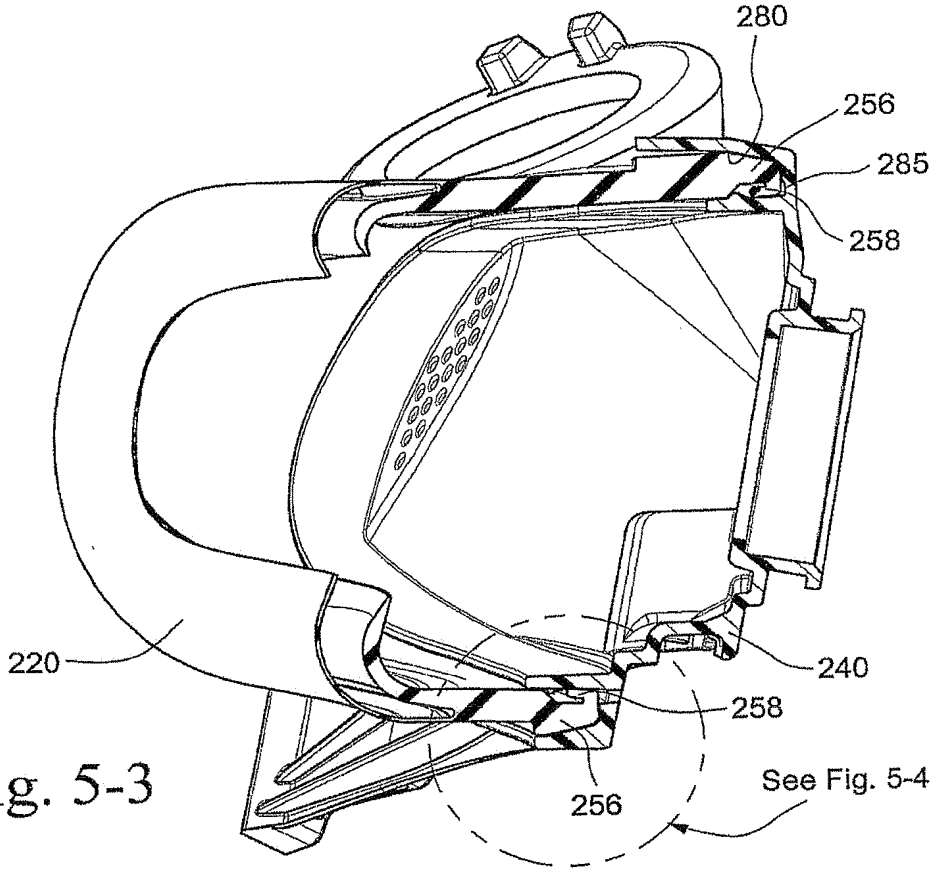


Fig. 5-2


280
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See Fig. 5-4

Fig. 5-3

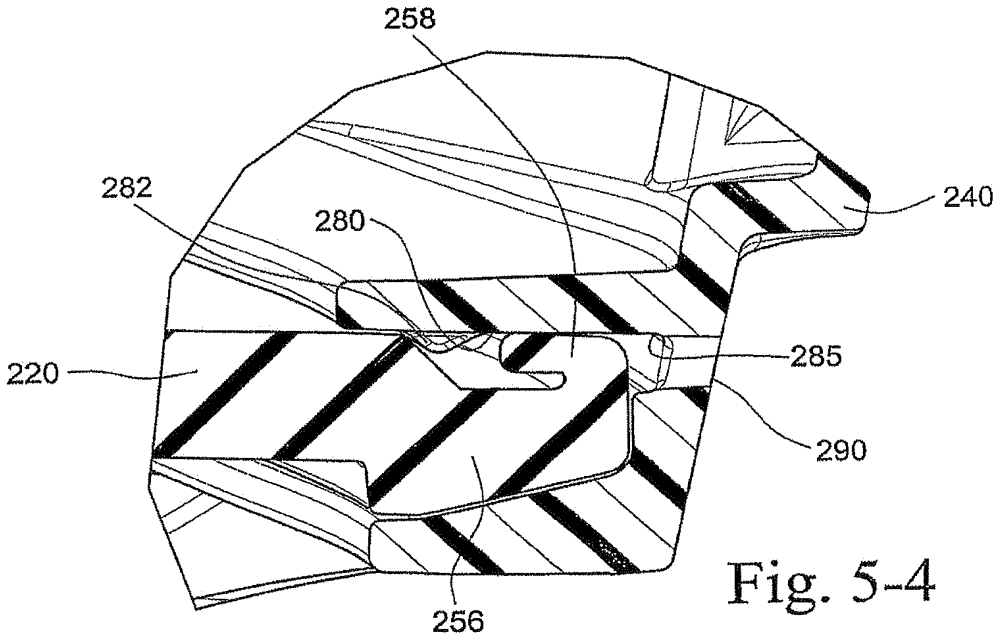
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Fig. 5-4

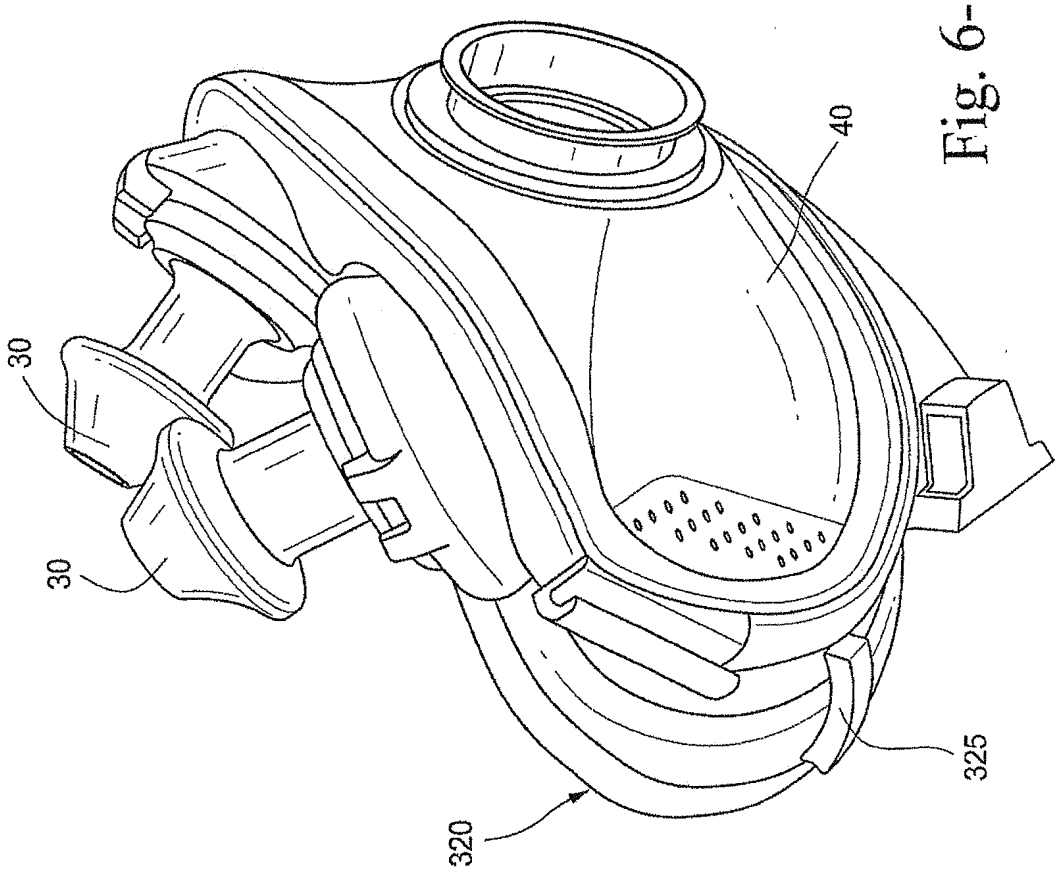

Fig. 6-1

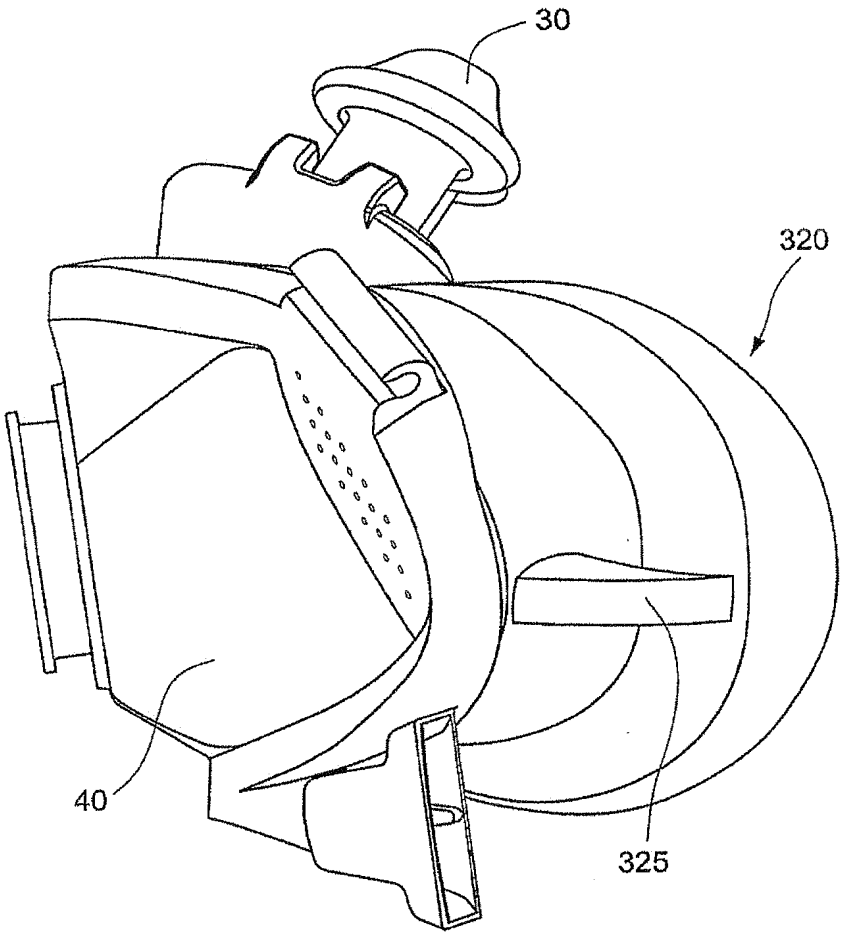

Fig. 6-2

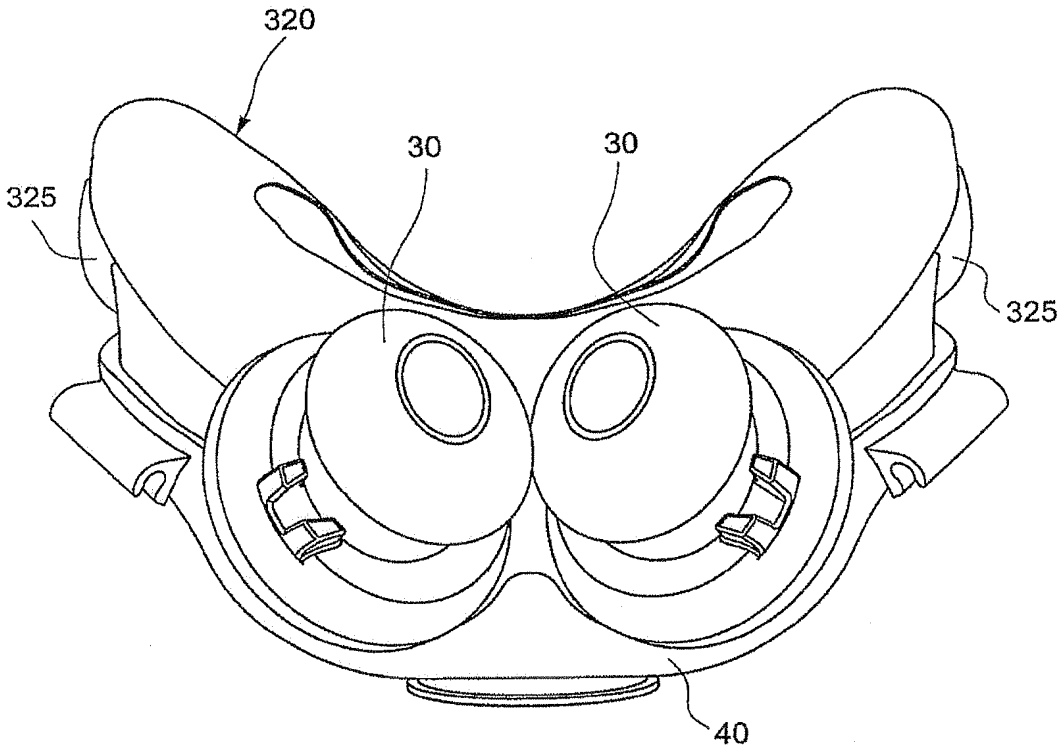

Fig. 6-3

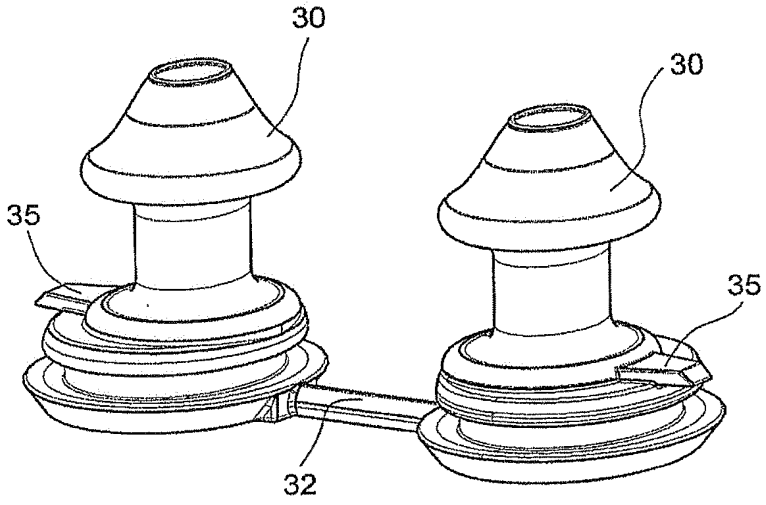

Fig. 7-1

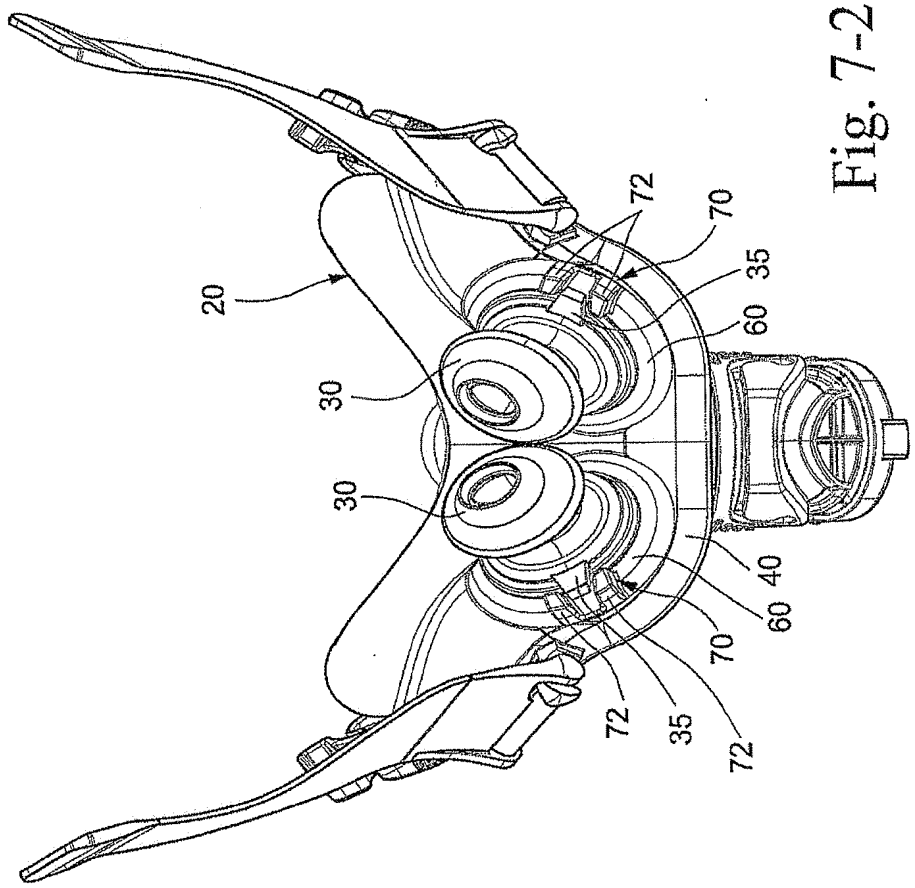

Fig. 7-2

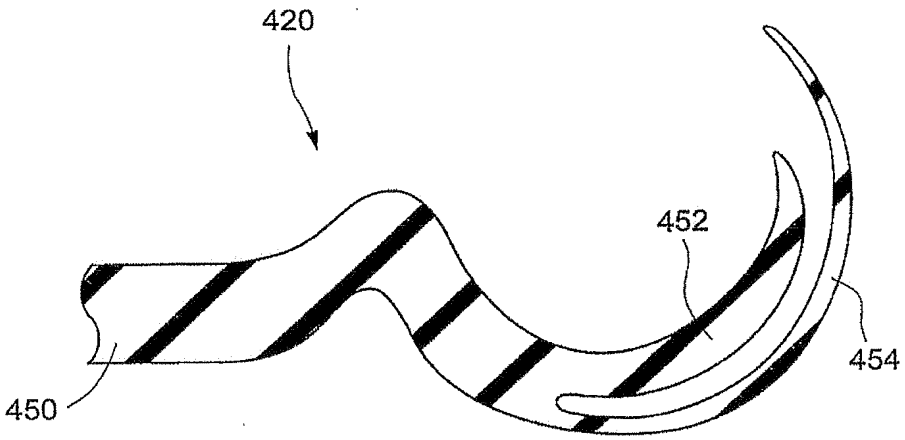

Fig. 8-1

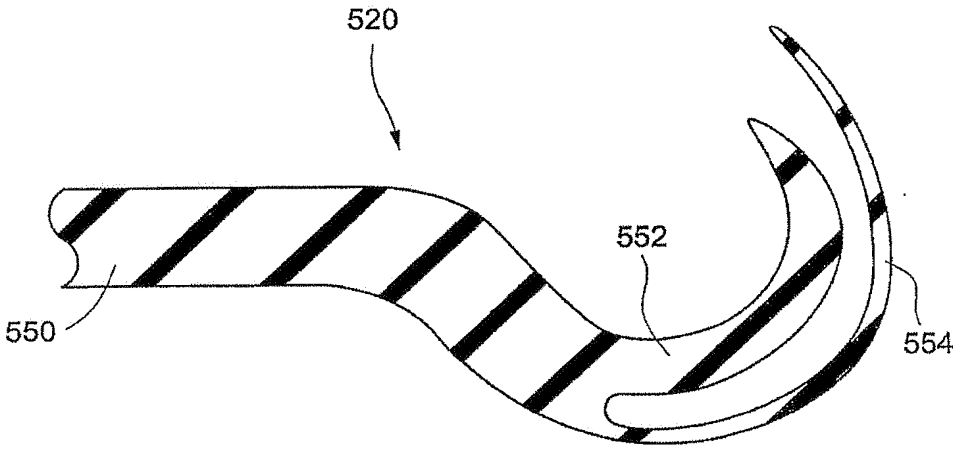

Fig. 9-1

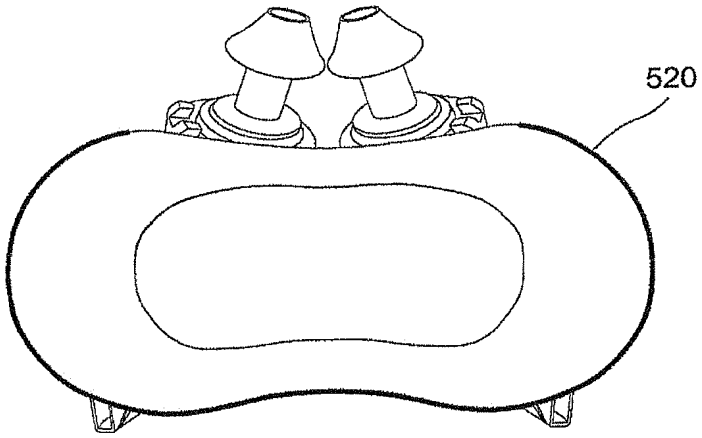

Fig. 9-2

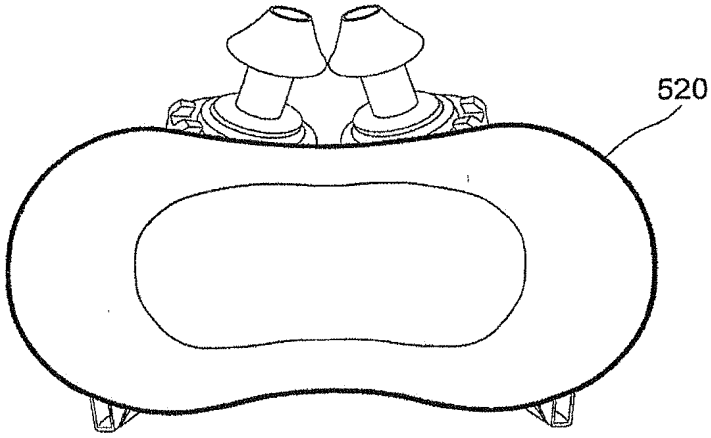

Fig. 9-3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2007/001456

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ***A61M 16/06*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI (IPC: A61M 16/-, A62B 18/- ; KEYWORDS; mask, interface, mouth, seal, cushion, pillow, pad, buffer, profile, +shape+, +section+, config+, question+, sickle+, curv+, roll+, semi-circ+)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/130903 A1 (RESMED LIMITED) 14 December 2006 See in particular figures 110 to 119.	11 to 15
X	WO 2004/022146 A1 (RESMED LIMITED) 18 March 2004 See in particular figures 6, 6A, 6B and 15 to 40.	11 to 15
X	EP 1258266 A1 (TIARA MEDICAL SYSTEMS, INC.) 20 November 2002 See figures 6 to 9.	11 to 15
X	FR 2823122 A1 (SCHEGERIN) 11 October 2002 See figure 1.	11 to 15

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 December 2007	20 DEC 2007
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **PETER T. WEST** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : (02) 6283 2108

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2007/001456

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
11 to 15 as requested by the Applicant.

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No:

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claim 1 to 10 are directed to a mouth cushion for a mask system, the cushion having *inter alia* a side wall, the side wall including support structures for nasal prongs and each support structure including an alignment indicator to aid correct assembly of the respective nasal prong. Claims 24 and 25 are directed to a nasal prong arrangement and to a method of assembling a nasal prong to a cushion respectively, each of the nasal prongs having a marking and/or tab to align the prong with a support structure. It is considered that the alignment indicator comprises a first distinguishing feature.

- Claims 11 to 15 are directed to a mouth cushion for a mask system, the cushion having *inter alia* an undercushion, and at least a part of the undercushion including a question mark or sickle-shape configuration when in cross-section. It is considered that this shape of the undercushion comprises a second distinguishing feature.

- Claim 23 is directed to a mask system to deliver breathable gas to a patient, the mask having a frame including a channel to retain a cushion and a recess that communicates with the channel and a hole that connects the recess to an exterior of the frame, the hole and recess proving a exit route for air contained within the channel. It is considered that this exit route comprises a third distinguishing feature.

- Claim 26 is directed to a mouth cushion for a mask system comprising a side wall, an undercushion, a membrane to seal around the patient's mouth, the side wall including support structures for nasal prongs and at least a portion of the undercushion including structures to encourage bending in use. It is considered that the structures to encourage bending comprise a fourth distinguishing feature.

Claim 16 to 22 are appended to claims 1 to 15.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2007/001456

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	2006130903	AU	2004308536	CN	1901961	CN	1973914
		EP	1701759	US	2006237017	US	2006283461
		US	2007144525	US	2007186930	WO	2005063328
WO	2004022146	AU	2003257270	AU	2003257271	AU	2003257273
		AU	2003257274	CN	1681551	CN	1681552
		CN	1681553	CN	1688358	EP	1334742
		EP	1539288	EP	1545673	EP	1545674
		EP	1545675	JP	2003175106	US	6812762
		US	6823869	US	6927613	US	7011090
		US	7088162	US	7216647	US	2003075180
		US	2003080799	US	2003090308	US	2004112384
		US	2004112385	US	2004112387	US	2004118406
		US	2005081858	US	2005151572	US	2006102185
		US	2007157934	WO	03023962	WO	03023963
		WO	2004022144	WO	2004022145	WO	2004022147
EP	1258266	BR	0201863	CA	2386686	MX	PA02005001
		US	7007696	US	2003019495		
FR	2823122	NONE					

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX